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*Admitted only in Maryland
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*Practice Limited to
Federal Agencies

July 8, 2003

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Utility Patent Application
Appl. No. 10/005,876; Filed: December 7, 2001
For: **Methods and Compositions for Synthesis of Nucleic Acid Molecules
Using Multiple Recognition Sites**
Inventors: CHESNUT *et al.*
Our Ref: 0942.5340002/RWE/BJD/JKM

Sir:

Transmitted herewith for appropriate action are the following documents:

1. First Supplemental Information Disclosure Statement;
2. List of cited references on Form PTO-1449 (102 sheets);
3. A copy of each reference cited on Form PTO-1449 (346 documents: **AL1-AL9, and AR1-AS102**); and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
July 8, 2003
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono
Attorney for Applicants
Registration No. 42,473

BJD/JKM/acr
Enclosures

SKGF_DC1:152096.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re application of:

Chesnut *et al.*

Appl. No. 10/005,876

Filed: December 7, 2001

For: **Methods and Compositions for
Synthesis of Nucleic Acid
Molecules Using Multiple
Recognition Sites**

Confirmation No. 7958

Art Unit: 1645

Examiner: *To Be Assigned*

Atty. Docket: 0942.5340002/RWE/BJD/JKM

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First Supplemental Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed electronically herewith, in connection with the above-captioned application. A copy of each document is also provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, concise explanation of the relevance of the non-English language documents AO6 and AM7 cited on Form PTO 1449:

Document AO6, WO 98/53056, is in the German language. An unverified English language abstract of document AO6 is attached as document AT100.

Document AM7, WO 99/25851, is in the Japanese language. An unverified English language abstract of document AM7 is attached as document AR101.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on

information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono
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Registration No. 42,473

Date: July 8, 2003

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.5430002/RWE/BJD/JKM	APPLICATION NO. 10/005,876
	APPLICANT Chesnut et al.	
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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	EP 0 160 571	11/06/1985	Europe			Yes No
	AM1	EP 0 220 009	04/29/1987	Europe			Yes No
	AN1	EP 0 300 422	01/25/1989	Europe			Yes No
	AO1	WO 90/11375	10/04/1990	WIPO			Yes No
	AP1	WO 91/02801	03/07/1991	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>1</u>	Abremski, K., and Gottesman, S., "Purification of the Bacteriophage λ xis Gene Product Required for λ Excisive Recombination," <i>J. Biol. Chem.</i> 257:9658-9662, The American Society of Biological Chemists (1982).
	AS	<u>1</u>	Abremski, K., and Hoess, R., "Bacteriophage P1 Site-specific Recombination. Purification and Properties of the Cre Recombinase Protein," <i>J. Biol. Chem.</i> 259:1509-1514, The American Society of Biological Chemists (1984).
	AT	<u>1</u>	Abremski, K., et al., "Bacteriophage P1 Cre-loxP Site-specific Recombination. Site-specific DNA Topoisomerase Activity of the Cre Recombination Protein," <i>J. Biol. Chem.</i> 261:391-396, The American Society of Biological Chemists (1986).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	EP 0 427 074	05/15/1991	Europe			Yes No
	AM2	WO 91/09957	07/11/1991	WIPO			Yes No
	AN2	WO 91/16427	10/31/1991	WIPO			Yes No
	AO2	WO 92/15694	09/17/1992	WIPO			Yes No
	AP2	WO 92/20791	11/26/1992	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>2</u>	Abremski, K., et al., "Studies on the Properties of P1 Site-Specific Recombination: Evidence for Topologically Unlinked Products Following Recombination," Cell 32:1301-1311, The MIT Press (1993).
AS	<u>2</u>	Adams, D.E., et al., "Cre-lox Recombination in <i>Escherichia coli</i> Cells. Mechanistic Differences from the <i>in Vitro</i> Reaction," J. Mol. Biol. 226:661-673, Academic Press (1992).
AT	<u>2</u>	Akagi, K., et al., "Cre-mediated somatic site-specific recombination in mice," Nucl. Acids Res. 25:1781-1788, Oxford University Press (1997).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	WO 92/22650	12/23/1992	WIPO			Yes No
	AM3	EP 0 542 466	05/19/1993	Europe			Yes No
	AN3	WO 93/15191	08/05/1993	WIPO			Yes No
	AO3	WO 93/19172	09/30/1993	WIPO			Yes No
	AP3	WO 94/03624	02/17/1994	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>3</u>	Aladjem, M.I., et al., "Positive Selection of FLP-Mediated Unequal Sister Chromatid Exchange Products in Mammalian Cells," <i>Mol. Cell. Biol.</i> 17:857-861, American Society for Microbiology (1997).
	AS	<u>3</u>	Albert, H., et al., "Site-specific integration of DNA into wild-type and mutant lox sites placed in the plant genome, " <i>Plant J.</i> 7:649-659, Blackwell Science Ltd. (1995).
	AT	<u>3</u>	Andrews, B.J., et al., "Interaction of the FLP Recombinase of the <i>Saccharomyces cerevisiae</i> 2 μ m Plasmid with Mutated Target Sequences," <i>Mol. Cell. Biol.</i> 6:2482-2489, American Society for Microbiology (1986).

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	AL4	CA 2,141,412	02/17/1994	Canada			Yes No
	AM4	WO 94/09127	04/28/1994	WIPO			Yes No
	AN4	WO 94/17176	08/04/1994	WIPO			Yes No
	AO4	WO 94/18333	08/18/1994	WIPO			Yes No
	AP4	WO 95/00555	01/05/1995	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>4</u>	Andrews, B.J., et al., "The FLP Recombinase of the 2 μ Circle DNA of Yeast: Interaction with Its Target Sequences," Cell 40:795-803, The MIT Press (1985).
	AS	<u>4</u>	Angelastro, J.M., et al., "Identification of diverse nerve growth factor-regulated genes by serial analysis of gene expression (SAGE) profiling," Proc. Natl. Acad. Sci. USA 97:10424-10429, National Academy of Sciences (September 2000).
	AT	<u>4</u>	Angrand, P.O., et al., "Inducible expression based on regulated recombination: a single vector strategy for stable expression in cultured cells," Nucl. Acids Res. 26:3263-3269, Oxford University Press (1998).

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	AL5	WO 96/04393	02/15/1996	WIPO			No
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	AM5	WO 96/30498	10/03/1996	WIPO			No
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	AN5	WO 96/40724	12/19/1996	WIPO			No
							Yes
	AO5	WO 97/06265	02/20/1997	WIPO			No
							Yes
	AP5	WO 97/09436	03/13/1997	WIPO			No

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	AR	<u>5</u>	Anton, M., and Graham, F.L., "Site-Specific Recombination Mediated by an Adenovirus Vector Expressing the Cre Recombinase Protein: a Molecular Switch for Control of Gene Expression," <i>J. Virol.</i> 69:4600-4606, American Society for Microbiology (1995).
	AS	<u>5</u>	Araki, H., et al., "Site-specific Recombinase, R, Encoded by Yeast Plasmid pSR1," <i>J. Mol. Biol.</i> 225:25-37, Academic Press (1992).
	AT	<u>5</u>	Argos, P., et al., "The integrase family of site-specific recombinases: regional similarities and global diversity," <i>EMBO J.</i> 5:433-440, IRL Press (1986).

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	AL6	WO 97/25446	07/17/1997	WIPO			Yes No
	AM6	WO 97/32481	09/12/1997	WIPO			Yes No
	AN6	WO 98/10086	03/12/1998	WIPO			Yes No
	AO6	WO 98/53056	11/26/1998	WIPO			Yes No
	AP6	WO 99/10488	03/04/1999	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Astumian, J.H., <i>et al.</i> , "Site-Specific Recombination between Cloned <i>attP</i> and <i>attB</i> Sites from the <i>Haemophilus influenzae</i> Bacteriophage HP1 Propagated in Recombination-Deficient <i>Escherichia coli</i> ," <i>J. Bacteriol.</i> 171:1747-1750, American Society for Microbiology (1989).
	AS	<u>6</u>	Atlung, T., <i>et al.</i> , "A versatile method for integration of genes and gene fusions into the λ attachment site of <i>Escherichia coli</i> ," <i>Gene</i> 107:11-17, Elsevier Science B.V. (1991).
	AT	<u>6</u>	Ausubel, F.M., <i>et al.</i> , "Maps of Plasmids," in <i>Current Protocols in Molecular Biology</i> , Ausubel, F.M., <i>et al.</i> , eds., John Wiley & Sons, Boston, MA, pp. 1.5.3-1.5.4 (1994).

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	AL7	WO 99/21977	05/06/1999	WIPO			Yes No
	AM7	WO 99/25851	05/27/1999	WIPO			Yes No X
	AN7	WO 99/55851	11/04/1999	WIPO			Yes No
	AO7	WO 00/12687	03/09/2000	WIPO			Yes No
	AP7	EP 1 035 208	09/13/2000	Europe			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	Ausubel, F.M., et al., "Mutagenesis by the Polymerase Chain Reaction," in <i>Current Protocols in Molecular Biology</i> , Ausubel, F.M., et al., eds., John Wiley & Sons, Boston, MA, pp. 8.5.1-8.5.9 (1991).
	AS	7	Ayres, E.K., et al., "Precise Deletions in Large Bacterial Genomes by Vector-mediated Excision (VEX). The <i>trfA</i> Gene of Promiscuous Plasmid RK2 is Essential for Replication in Several Gram-negative Hosts," <i>J. Mol. Biol.</i> 230:174-185, Academic Press (1993).
	AT	7	Babineau, D., et al., "The FLP Protein of the 2-micron Plasmid of Yeast. Purification of the Protein from <i>Escherichia coli</i> Cells Expressing the Cloned <i>FLP</i> Gene," <i>J. Biol. Chem.</i> 260:12313-12319, The American Society of Biological Chemists (1985).

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	AL8	WO 00/60091	10/12/2000	WIPO			Yes No
	AM8	WO 01/05961	01/25/2001	WIPO			Yes No
	AN8	WO 01/07572	02/01/2001	WIPO			Yes No
	AO8	WO 01/11058	02/15/2001	WIPO			Yes No
	AP8	WO 01/62892	08/30/2001	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	8	Backman, K., et al., "Use of Synchronous Site-Specific Recombination In Vivo to Regulate Gene Expression," <i>Bio/Technology</i> 2:1045-1049, Nature Publishing Company (1984).
	AS	8	Bai, C., et al., "SKP1 Connects Cell Cycle Regulators to the Ubiquitin Proteolysis Machinery through a Novel Motif, the F-Box," <i>Cell</i> 86:263-274, Cell Press (1996).
	AT	8	Balakrishnan, R., et al., "A gene cassette for adapting <i>Escherichia coli</i> strains as hosts for att-Int-mediated rearrangement and p_L expression vectors," <i>Gene</i> 138:101-104, Elsevier Science B.V. (1994).

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	AL9	WO 02/05294	01/17/2002	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	9	Bayley, C.C., et al., "Exchange of gene activity in transgenic plants catalyzed by the Cre-lox site specific recombination system," <i>Plant Mol. Biol.</i> 18:353-361, Kluwer Academic Publishers (1992).
AS	9	Bernard, P., et al., "Positive-selection vectors using the F plasmid ccdB killer gene," <i>Gene</i> 148:71-74, Elsevier Science B.V. (1994).
AT	9	Bernard, P. et al., "The F Plasmid CcdB Protein Induces Efficient ATP-dependent DNA Cleavage by Gyrase," <i>J. Mol. Biol.</i> 234:534-541, Academic Press (1993).

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	AO						Yes No
	AP						Yes No

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AR	<u>10</u>	Bernard, P., "Positive Selection of Recombinant DNA by CcdB," <i>BioTechniques</i> 21:320-323, Eaton Publishing Company (1996).
AS	<u>10</u>	Bernard, P., and Couturier, M., "Cell Killing by the F plasmid CcdB Protein Involves Poisoning of DNA-Topoisomerase II Complexes," <i>J. Mol. Biol.</i> 226:735-745, Academic Press (1992).
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	AR	<u>11</u>	Betz, U.A.K., et al., "Bypass of lethality with mosaic mice generated by Cre-loxP-mediated recombination," <i>Curr. Biol.</i> 6:1307-1316, Current Biology Ltd. (1996).
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	AR	<u>15</u>	Buchholz, F., et al., "A simple assay to determine the functionality of Cre or FLP recombination targets in genomic manipulation constructs," <i>Nucl. Acids Res.</i> 24:3118-3119, Oxford University Press (1996).
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	AR	<u>19</u>	Cigan, A.M., et al., "Mutational Analysis of the <i>HIS4</i> Translational Initiator Region in <i>Saccharomyces cerevisiae</i> ," <i>Mol. Cell. Biol.</i> 8:2964-2975, American Society for Microbiology (1988).
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	AR	<u>25</u>	Degryse, E., "In vivo intermolecular recombination in <i>Escherichia coli</i> : application to plasmid constructions," <i>Gene</i> 170:45-50, Elsevier Science B.V. (1996).
	AS	<u>25</u>	Deng, M.-D., and Coleman, J.R., "Ethanol Synthesis by Genetic Engineering in Cyanobacteria," <i>Appl. Environ. Microbiol.</i> 65:523-528, American Society for Microbiology (February 1999).
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	AR	<u>31</u>	Gage, P.J., et al., "A Cell-Free Recombination System for Site-Specific Integration of Multigenic Shuttle Plasmids into Herpes Simplex Type 1 Genome," <i>J. Virol.</i> 66:5509-5515, American Society for Microbiology (1992).
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	AR	<u>39</u>	Hoekstra, M.F., et al., "Shuttle Mutagenesis: Bacterial Transposons for Genetic Manipulations in Yeast," <i>Meth. Enzymol.</i> 194:329-342, Academic Press (1991).
	AS	<u>39</u>	Hoess, R.H., and Abremski, K., "Interaction of the bacteriophage P1 recombinase Cre with the recombining site loxP," <i>Proc. Natl. Acad. Sci. USA</i> 81:1026-1029, National Academy of Sciences (1984).
	AT	<u>39</u>	Hoess, R.H., and Abremski, K., "The Cre-lox Recombination System," in <i>Nucleic Acids and Molecular Biology</i> , Volume 4, Eckstein, F., and Lilley, D.M.J., eds., Springer-Verlag, Berlin, Germany, pp 99-109 (1990).

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	AR	<u>40</u>	Hoess, R.H., et al., "The role of the loxP spacer region in P1 site-specific recombination," Nucl. Acids Res. 14:2287-2300, IRL Press Limited (1986).
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	AT	<u>40</u>	Hoess, R.H., and Abremski, K., "Mechanism of Strand Cleavage and Exchange in the Cre-lox Site-specific Recombination System," J. Mol. Biol. 181:351-362, Academic Press (1985).

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	AR	<u>46</u>	Kitts, P.A., and Nash, H.A., "Bacteriophage Lambda Site-specific Recombination Proceeds with a Defined Order of Strand Exchanges," <i>J. Mol. Biol.</i> 204:95-107, Academic Press (1988).
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	AR	<u>47</u>	Kozak, M., "An analysis of 5'-noncoding sequences from 699 vertebrate messenger RNAs," <i>Nucl. Acids Res.</i> 15:8125-8148, IRL Press (1987).
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	AR	<u>48</u>	Krafte, D.S., et al., "Stable Expression and Functional Characterization of a Human Cardiac Na ⁺ Channel Gene in Mammalian Cells," <i>J. Mol. Cell. Cardiol.</i> 27:823-830, Academic Press (1995).
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	AT	<u>53</u>	Lorbach, E., et al., "Site-specific Recombination in Human Cells Catalyzed by Phage λ Integrase Mutants," <i>J. Mol. Biol.</i> 296:1175-1181, Academic Press (March 2000).

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	AT	<u>54</u>	Mackie, G.A., "Nucleotide Sequence of the Gene for Ribosomal Protein S20 and Its Flanking Regions," <i>J. Biol. Chem.</i> 256:8177-8182, The American Society of Biological Chemists (1981).

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ATTY. DOCKET NO.
 0942.5430002/RWE/BJD/JKM

APPLICATION NO.
 10/005,876

APPLICANT
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	AT	<u>55</u>	Maeser, S., and Kahmann, R., "The Gin recombinase of phage Mu can catalyse site-specific recombination in plant protoplasts," <i>Mol. Gen. Genet.</i> 230:170-176, Springer-Verlag (1991).

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	AR	<u>83</u>	Segall, A.M., and Nash, H.A., "Synaptic intermediates in bacteriophage lambda site-specific recombination: integrase can align pairs of attachment sites," <i>EMBO J.</i> 12:4567-4576, Oxford University Press (1993).
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	AT	<u>86</u>	Snaith, M.R., et al., "Multiple cloning sites carrying loxP and FRT recognition sites for the Cre and FLP site-specific recombinases," <i>Gene</i> 166:173-174, Elsevier Science B.V. (1995).

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.5430002/RWE/BJD/JKM	APPLICATION NO. 10/005,876
	APPLICANT Chesnut <i>et al.</i>	
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
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